

Entry of the foregoing amendments, reconsideration and re-examination of the subject application, as amended pursuant to and consistent with 37 C.F.R. §1.116, and in light of the remarks which follow are respectfully requested.

By the present amendments, claim 44 has been amended to overcome the §112 first paragraph rejection. This amendment finds support at page 12, definition of “prolonged suppression”.

Claims 44-46 and 49-55 stand rejected under 35 U.S.C. §112 first paragraph based on inadequate written description. It is anticipated that this rejection will be overcome by the present amendment of claim 44.

Indeed, the claim now recites the precise definition of “prolonged suppression” from page 12 of the as-filed application. Hence, there cannot be a written description issue now as the present invention clearly envisioned the invention as-filed.

Also, the application provides express support for concurrent administration of a TD antigen and gp39 antagonist at page 13, lines 5-10 of subject application. Withdrawal of the §112 first paragraph rejection of claims 44-46 and 49-55 is respectfully requested.

Claims 44-46, 49 and 51-53 stand rejected under 35 U.S.C. §103 as being unpatentable over Cobbold et al. in view of Lederman et al., or Armitage et al.

Essentially, Applicants maintain that none of the references teaches or suggests concurrent administration of a soluble TD antigen (e.g., therapeutic antibody) and a gp39 antagonist, specifically an anti-gp39 antibody in order to achieve prolonged suppression of humoral immunity (wherein prolonged suppression of immunity means that antibodies against TD antigen remain suppressed after gp39 antibody administration has been terminated).

As was argued during prosecution of the parent application, now patented, this is not suggested by any of the prior art references. Rather Cobbold, teaches the use of CD4 specific antibodies, not gp39 antibodies, to achieve tolerance to an antigen. This is absolutely no suggestion from Cobbold that an anti-gp39 antibody could be used to tolerize a host against a specific antigen. Moreover, this could not have been reasonably predicted, especially based on the fact that achieving tolerance was and remains highly unpredictable. Essentially, it cannot be extrapolated based on the fact that anti-CD4 antibodies induce tolerance to antigen, that similar effects would be achieved with antibodies to another T cell antigen.

The secondary references, Lederman et al., and Armitage et al., further do not teach or suggest the invention. While both of these references teach the use of an anti-gp39 antibody to suppress humoral immunity in a global manner, i.e., to a plurality of different antigens, neither teaches or suggests that the co-administration of an anti-gp39 antibody and a soluble TD antigen would achieve prolonged tolerance to a specific TD antigen i.e., after gp39 antibody administration has been discontinued.

As was explained during prosecution of the parent application, it was truly unexpected that a gp39 antagonist would tolerize a subject to a specific antigen. In fact, this effect is still unexplained, but is hypothesized by the inventors to be attributable to an effect on T cells that is not suggested by the prior art.

As explained during prosecution of the parent application, the present invention surprisingly discovered that a gp39 antibody has a prolonged effect on T cell function, and specifically results in the inability of T cells to respond to specific antigens to which they become exposed in conjunction with a gp39 antibody. This prolonged effect on T cells by gp39 antibodies is not suggested by Cobbold, Lederman or Armitage. Rather, these references only teach that a gp39 antibody would elicit a transient, global effect on antibody production by B cells. The references are silent with report to a prolonged effect of a gp39 antagonist on T cells, that results in suppressed antibody prevention by B cells to a particular TD antigen.

Withdrawal of the §103 rejection of claims 44-46, 49 and 51-53 based on Cobbold et al, Lederman et al. and Armitage et al. is therefor respectfully requested.

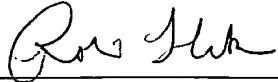
Claims 50,54 and 55 are further not suggested by the same prior art in view of Ramanathan et al. This rejection is traversed based on the fact that this reference merely suggests the use of IL-4 specific antagonists to inhibit allergic responses. The reference is completely silent with respect to the use of an anti-gp39 antagonist to provide for a prolonged antigen specific effect on T cells.

Withdrawal of the §103 rejection of claims 50, 54 and 55 based on the above discussed references in view of Ramanathan et. al. is therefor respectfully requested.

Based on the foregoing, this application is believed to be in condition for allowance.
A Notice to that effect is respectfully solicited.

Respectfully submitted,

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Attachment: Appendix

APPENDIX

IN THE CLAIMS:

44. (Twice Amended) A method for inducing prolonged humoral suppression in a subject in need of such prolonged humoral immune ~~suppression~~ response, to a soluble thymus dependent (TD) antigen which method comprises:

(i) administering a soluble TD antigen to which a humoral ~~immune~~ reaction response is to be suppressed; and

(ii) administering an amount of an anti-gp39 antibody or a fragment thereof that binds gp39, in an amount effective to provide for prolonged humoral immune suppression to said soluble TD antigen, wherein ~~prolonged humoral immune suppression means that antibody production remains suppressed after the anti-gp39 antibody has been cleared from the subject~~ administration of (i) and (ii) is effected concurrently, and wherein prolonged humoral immune suppression means that suppression of antibody prevention against the antigen is maintained after administration of said anti-gp39 has been terminated.



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